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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/580,476	05/26/2000	Edwin G. Westaway	37264.6.0	8898

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Fredrikson & Byron PA
1100 International Centre
900 Second Avenue South
Minneapolis, MN 55402-3397

EXAMINER
GUZO, DAVID

ART UNIT	PAPER NUMBER
1636	11

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/580,476	Applicant(s) WESTAWAY ET AL.	
	Examiner David Guzo	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2002*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *40-42* is/are allowed.

6)☒ Claim(s) *1-4,6-20,24-32,35-39,43-53 and 55-64* is/are rejected.

7)☒ Claim(s) *5,21-23,33,34,54 and 65* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

Detailed Action

Receipt of certified copies of the Australian applications is acknowledged.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-20, 24-32, 35-39, 43-53 and 55-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained for reasons of record in the previous Office Action (Paper #6) and for reasons outlined below.

Applicants traverse this rejection by indicating that the art with regard to generation of flavivirus replicons was not unpredictable or poorly developed and cite several articles published after the effective filing date of the instant application wherein applicants assert that the authors of said papers developed flavivirus replicon vectors which followed the design of flavivirus replicon vectors outlined by applicants in the instant specification. Applicants assert that the present application does not claim the development of stable cell lines expressing structural flavivirus proteins but instead claims cell lines which support replication of flavivirus replicons with inserted antibiotic resistance genes as vectors for establishing cell lines which stably support expression of inserted heterologous genes and/or sequences. Applicants assert that the teachings

provided using the Kunjin virus would permit the skilled artisan to practice the invention with other flaviviruses.

Applicant's arguments filed 4/23/02 have been fully considered but they are not persuasive. First, it is noted that the references cited by applicants were all published after the filing date of the instant application and cannot be used to define the state of the art at the time the instant invention was made (See *In re Glass*, 181 USPQ 31 CCPA 1974). While it is acknowledged that the references cited utilize some similar types of constructs in the generation of replicons, said references do not enable the claimed invention. For example, the claimed gene expression system requires the generation of cell lines that can support replication of flavivirus replicons that can **comprise and express flavivirus structural proteins**. Applicants provide no teachings on how these cell lines are to be generated and given the cytotoxicity of many flavivirus proteins, generation of these cell lines would be a trial and error endeavor. Also, the teachings in the post filing references cited by applicants involve generation of novel replicon constructs and utilize techniques not taught in the instant specification and said teachings do not address how the instant invention would be practiced with flaviviruses such as HCV.

Claims 1-4, 6-20, 24-32, 35-39, 43-53 and 55-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicants traverse this rejection by reiterating arguments made in response to the 35 USC 112, 1st paragraph (enablement) rejection. Specifically, applicants appear to indicate that the teachings concerning Kunjin virus would have provided the skilled artisan with a description of other flavivirus replicons, expression systems and cell lines capable of supporting any flavivirus replicon replication and expression of flavivirus structural proteins. Applicants assert that description of every species of a claimed genus is not necessary and that the instant specification provides a disclosure that reasonably conveys to the skilled artisan that applicants had possession of the claimed genus at the time of applicants' invention.

Applicants' arguments have been considered but are not persuasive. Applicants appear to be asserting that since the specification is enabling, it also provides a written description of the claimed genus. This argument is not on point because the issue in question is whether applicants have provided a description of the claimed replicons, transformed cell lines and expression systems sufficient to cause the skilled artisan to conclude that applicants were in possession of the claimed genus. Clearly, in the present case, applicants provide one example of the claimed genus and recite the other members of the genus by functional characteristics only. The description of one member of the genus would not provide a description of replicons based upon HCV or

other members of the diverse flavivirus group or cell lines capable of stably replicating replicons of flaviviruses such as HCV, etc. and capable of tolerating expression of potentially cytotoxic flavivirus structural proteins. Clearly, given the diversity of viruses in the flavivirus group, given the lack of a description of the cells that would be capable of supporting replicons derived from flaviviruses such as HCV, given the lack of knowledge concerning the packaging mechanisms of flaviviruses, etc. it must be considered that the skilled artisan would not conclude that applicants were in possession of the claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38-39 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 38-39 are vague in the use of the term "as herein described".

Claim 44 is vague in the recitation of a vector "...engineered to prevent recombination...".

These rejections have not been traversed by applicants and therefore they are maintained for reasons of record.

Claims 40-42 are allowed.

Claims 5, 21-23, 33-34 and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be sent directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding or relating to attachments to this Office Action should be directed to Patent Analyst Zeta Adams whose telephone number is (703) 305-3291.

David Guzo
July 9, 2002

DAVID GUZO
PRIMARY EXAMINER